

§ 864.9750

in subpart E of part 807 of this chapter subject to § 864.9.

[45 FR 60650, Sept. 12, 1980, as amended at 63 FR 59226, Nov. 3, 1998]

§ 864.9750 Heat-sealing device.

(a) *Identification.* A heat-sealing device is a device intended for medical purposes that uses heat to seal plastic bags containing blood or blood components.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 864.9.

[45 FR 60650, Sept. 12, 1980, as amended at 65 FR 2311, Jan. 14, 2000]

§ 864.9875 Transfer set.

(a) *Identification.* A transfer set is a device intended for medical purposes that consists of a piece of tubing with suitable adaptors used to transfer blood or plasma from one container to another.

(b) *Classification.* Class II (performance standards).

[45 FR 60651, Sept. 12, 1980]

PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES

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866.3140 *Corynebacterium* spp. serological reagents.

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866.3165 *Cryptococcus neoformans* serological reagents.

866.3175 Cytomegalovirus serological reagents.

866.3200 *Echinococcus* spp. serological reagents.

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866.3240 Equine encephalomyelitis virus serological reagents.

866.3250 *Erysipelothrix rhusiopathiae* serological reagents.

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 866.3270 *Flavobacterium* spp. serological reagents.
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 866.3290 Gonococcal antibody test (GAT).
 866.3300 *Haemophilus* spp. serological reagents.
 866.3305 Herpes simplex virus serological reagents.
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 866.3330 Influenza virus serological reagents.
 866.3340 *Klebsiella* spp. serological reagents.
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 866.3470 Reovirus serological reagents.
 866.3480 Respiratory syncytial virus serological reagents.
 866.3490 Rhinovirus serological reagents.
 866.3500 Rickettsia serological reagents.
 866.3510 Rubella virus serological reagents.
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 866.3550 *Salmonella* spp. serological reagents.
 866.3600 *Schistosoma* spp. serological reagents.
 866.3610 Endotoxin assay.
 866.3630 *Serratia* spp. serological reagents.
 866.3660 *Shigella* spp. serological reagents.
 866.3680 *Sporothrix schenckii* serological reagents.
 866.3700 *Staphylococcus aureus* serological reagents.
 866.3720 *Streptococcus* spp. exoenzyme reagents.
 866.3740 *Streptococcus* spp. serological reagents.
 866.3780 *Toxoplasma gondii* serological reagents.
 866.3820 *Treponema pallidum* nontreponemal test reagents.
 866.3830 *Treponema pallidum* treponemal test reagents.
 866.3850 *Trichinella spiralis* serological reagents.
 866.3870 *Trypanosoma* spp. serological reagents.

866.3900 Varicella-zoster virus serological reagents.
 866.3930 *Vibrio cholerae* serological reagents.
 866.3940 West Nile virus serological reagents.

Subpart E—Immunology Laboratory Equipment and Reagents

866.4100 Complement reagent.
 866.4500 Immunoelectrophoresis equipment.
 866.4520 Immunofluorometer equipment.
 866.4540 Immunonephelometer equipment.
 866.4600 Ouchterlony agar plate.
 866.4700 Automated fluorescence in situ hybridization (FISH) enumeration systems.
 866.4800 Radial immunodiffusion plate.
 866.4830 Rocket immunoelectrophoresis equipment.
 866.4900 Support gel.

Subpart F—Immunological Test Systems

866.5040 Albumin immunological test system.
 866.5060 Prealbumin immunological test system.
 866.5065 Human allotypic marker immunological test system.
 866.5080 α -1-antichymotrypsin immunological test system.
 866.5090 Antimitochondrial antibody immunological test system.
 866.5100 Antinuclear antibody immunological test system.
 866.5110 Antiparietal antibody immunological test system.
 866.5120 Antismooth muscle antibody immunological test system.
 866.5130 α -1-antitrypsin immunological test system.
 866.5150 Bence-Jones proteins immunological test system.
 866.5160 β -globulin immunological test system.
 866.5170 Breast milk immunological test system.
 866.5200 Carbonic anhydrase B and C immunological test system.
 866.5210 Ceruloplasmin immunological test system.
 866.5220 Cohn fraction II immunological test system.
 866.5230 Colostrum immunological test system.
 866.5240 Complement components immunological test system.
 866.5250 Complement C_1 inhibitor (inactivator) immunological test system.
 866.5260 Complement C_{3b} inactivator immunological test system.
 866.5270 C-reactive protein immunological test system.
 866.5320 Properdin factor B immunological test system.
 866.5330 Factor XIII, A, S, immunological test system.

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866.5340 Ferritin immunological test system.
866.5350 Fibrinopeptide A immunological test system.
866.5360 Cohn fraction IV immunological test system.
866.5370 Cohn fraction V immunological test system.
866.5380 Free secretory component immunological test system.
866.5400 *Alpha*-globulin immunological test system.
866.5420 *Alpha*-1-glycoproteins immunological test system.
866.5425 *Alpha*-2-glycoproteins immunological test system.
866.5430 *Beta*-2-glycoprotein I immunological test system.
866.5440 *Beta*-2-glycoprotein III immunological test system.
866.5460 Haptoglobin immunological test system.
866.5470 Hemoglobin immunological test system.
866.5490 Hemopexin immunological test system.
866.5500 Hypersensitivity pneumonitis immunological test system.
866.5510 Immunoglobulins A, G, M, D, and E immunological test system.
866.5520 Immunoglobulin G (Fab fragment specific) immunological test system.
866.5530 Immunoglobulin G (Fc fragment specific) immunological test system.
866.5540 Immunoglobulin G (Fd fragment specific) immunological test system.
866.5550 Immunoglobulin (light chain specific) immunological test system.
866.5560 Lactic dehydrogenase immunological test system.
866.5570 Lactoferrin immunological test system.
866.5580 *Alpha*-1-lipoprotein immunological test system.
866.5590 Lipoprotein X immunological test system.
866.5600 Low-density lipoprotein immunological test system.
866.5620 *Alpha*-2-macroglobulin immunological test system.
866.5630 *Beta*-2-microglobulin immunological test system.
866.5640 Infectious mononucleosis immunological test system.
866.5660 Multiple autoantibodies immunological test system.
866.5680 Myoglobin immunological test system.
866.5700 Whole human plasma or serum immunological test system.
866.5715 Plasminogen immunological test system.
866.5735 Prothrombin immunological test system.
866.5750 Radioallergosorbent (RAST) immunological test system.

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866.5765 Retinol-binding protein immunological test system.
866.5775 Rheumatoid factor immunological test system.
866.5785 Anti-Saccharomyces cerevisiae (S. cerevisiae) antibody (ASCA) test systems.
866.5800 Seminal fluid (sperm) immunological test system.
866.5820 Systemic lupus erythematosus immunological test system.
866.5860 Total spinal fluid immunological test system.
866.5870 Thyroid autoantibody immunological test system.
866.5880 Transferrin immunological test system.
866.5890 Inter-*alpha* trypsin inhibitor immunological test system.

Subpart G—Tumor Associated Antigen Immunological Test Systems

866.6010 Tumor associated antigen immunological test system.
866.6020 Immunomagnetic circulating cancer cell selection and enumeration system.

AUTHORITY: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

SOURCE: 47 FR 50823, Nov. 9, 1982, unless otherwise noted.

Subpart A—General Provisions

§ 866.1 Scope.

(a) This part sets forth the classification of immunology and microbiology devices intended for human use that are in commercial distribution.

(b) The identification of a device in a regulation in this part is not a precise description of every device that is, or will be, subject to the regulation. A manufacturer who submits a pre-market notification submission for a device under part 807 may not show merely that the device is accurately described by the section title and identification provisions of a regulation in this part, but shall state why the device is substantially equivalent to other devices, as required by § 807.87.

(c) To avoid duplicative listings, an immunology and microbiology device that has two or more types of uses (e.g., used both as a diagnostic device and as a microbiology device) is listed only in one subpart.

(d) References in this part to regulatory sections of the Code of Federal

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Regulations are to chapter I of title 21, unless otherwise noted.

(e) Guidance documents referenced in this part are available on the Internet at <http://www.fda.gov/cdrh.guidance.html>.

[52 FR 17733, May 11, 1987, as amended at 68 FR 5827, Feb. 5, 2003]

§ 866.3 Effective dates of requirement for premarket approval.

A device included in this part that is classified into class III (Premarket approval) shall not be commercially distributed after the date shown in the regulation classifying the device unless the manufacturer has an approval under section 515 of the act (unless an exemption has been granted under section 520(g)(2) of the act). An approval under section 515 of the act consists of FDA's issuance of an order approving an application for premarket approval (PMA) for the device or declaring completed a product development protocol (PDP) for the device.

(a) Before FDA requires that a device commercially distributed before the enactment date of the amendments, or a device that has been found substantially equivalent to such a device, has an approval under section 515 of the act FDA must promulgate a regulation under section 515(b) of the act requiring such approval, except as provided in paragraphs (b) and (c) of this section. Such a regulation under section 515(b) of the act shall not be effective during the grace period ending on the 90th day after its promulgation or on the last day of the 30th full calendar month after the regulation that classifies the device into class III is effective, whichever is later. See section 501(f)(2)(B) of the act. Accordingly, unless an effective date of the requirement for premarket approval is shown in the regulation for a device classified into class III in this part, the device may be commercially distributed without FDA's issuance of an order approving a PMA or declaring completed a PDP for the device. If FDA promulgates a regulation under section 515(b) of the act requiring premarket approval for a device, section 501(f)(1)(A) of the act applies to the device.

(b) Any new, not substantially equivalent, device introduced into commercial

distribution on or after May 28, 1976, including a device formerly marketed that has been substantially altered, is classified by statute (section 513(f) of the act) into class III without any grace period and FDA must have issued an order approving a PMA or declaring completed a PDP for the device before the device is commercially distributed unless it is reclassified. If FDA knows that a device being commercially distributed may be a "new" device as defined in this section because of any new intended use or other reasons, FDA may codify the statutory classification of the device into class III for such new use. Accordingly, the regulation for such a class III device states that as of the enactment date of the amendments, May 28, 1976, the device must have an approval under section 515 of the act before commercial distribution.

(c) A device identified in a regulation in this part that is classified into class III and that is subject to the transitional provisions of section 520(1) of the act is automatically classified by statute into class III and must have an approval under section 515 of the act before being commercially distributed. Accordingly, the regulation for such a class III transitional device states that as of the enactment date of the amendments, May 28, 1976, the device must have an approval under section 515 of the act before commercial distribution.

[52 FR 17733, May 11, 1987; 52 FR 22577, June 12, 1987]

§ 866.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

The exemption from the requirement of premarket notification (section 510(k) of the act) for a generic type of class I or II device is only to the extent that the device has existing or reasonably foreseeable characteristics of commercially distributed devices within that generic type or, in the case of in vitro diagnostic devices, only to the extent that misdiagnosis as a result of using the device would not be associated with high morbidity or mortality. Accordingly, manufacturers of any commercially distributed class I or II device for which FDA has granted an exemption from the requirement of